

# **EXHIBIT 622**

June 10, 2010

Jimmy Williamson  
Williamson & Rusnak  
4310 Yoakum Blvd.  
Houston, Texas 77006

Re: Mimi Rivera-Vega DOB: 4-10-1973

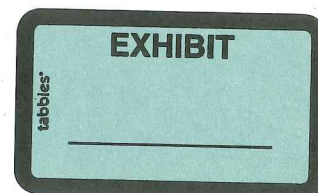
Dear Mr. Williamson:

I have been asked to provide a report regarding issues surrounding the death of Mimi Rivera-Vega, who was my patient from 2002 until her death in 2008. All of my opinions are expressed to a reasonable degree of medical probability. I have been asked, using my background, education, and experience, to formulate an opinion on the issue of whether Digitek® was a substantial factor and proximate cause toward Ms. Vega's death and to what extent this recalled product had an effect of her life prior to her death.

The opinions herein are based on my review of the materials provided to me, my medical knowledge, knowledge of the medical and scientific literature and various FDA documents, my education, training and over eleven years of practice as a doctor of internal medicine and cardiology, my experience in differential diagnosis as used in my clinical practice, as well as Ms. Vega's clinical presentation and my care and treatment of her for approximately six years.

Page 1 of 22

PLAINTIFFS' EXHIBITS 013876



I. Background and Qualifications

1. I am a cardiologist practicing at the Texas Heart Institute and St. Luke's Episcopal Hospital in Houston, Texas. I am board certified in Cardiology and I am a clinical assistant professor of medicine at Baylor College of Medicine and at The University of Texas Medical School at Houston. In addition, I hold the title of Medical Director for Mechanical Support Devices for Heart Failure at the Texas Heart Institute. My training includes an internship and residency in internal medicine and a fellowship in cardiology, heart failure and heart transplantation. I have been practicing as a specialist in cardiology, heart failure and heart transplantation and mechanical assist devices at the Texas Heart Institute for the last 11 years. During this time I have been responsible for the care of thousands of patients with heart failure, hundreds of patients before and after heart transplant and hundreds of patients before and after implantation of artificial heart support pump devices, including Mimi Rivera-Vega. I have a large practice of patients with all forms of heart disease and mostly heart failure. I have also been involved both as a primary caretaker and consultant in the care of patients with heart failure and non-ischemic cardiomyopathy and patients managed with the use of Digitek® (Digoxin) as well as the training and supervision of residents and fellows from the Baylor College of Medicine and The University

of Texas Medical School at Houston. Based on my knowledge of cardiac literature and over 11 years of experience treating heart failure patients, I am well aware of the risks and benefits of cardiac glycosides, including Digitek® and other digoxin drug products.

2. I take care of patients with the entire spectrum of cardiac diseases, including, but not limited to, hypertension, heart failure, atherosclerosis, cardiac arrhythmias, acute and chronic myocardial infarction, lipid abnormalities, heart muscle abnormalities, thromboembolic problems. My principal areas of research, clinical and teaching activities focus on heart failure and heart transplantation and mechanical assist devices including medical, pharmacological and interventional therapies for heart failure. As part of my clinical practice I am familiar with the risks, benefits, adverse events and toxicities in the medications used to treat heart failure, including digoxin, and have lectured, taught and published on the subject.

3. In the past 10 years, I have authored the following publication which addresses digoxin therapy, and many others dealing with all aspect of heart failure treatments:

The textbook: "Congestive Heart Failure- Contemporary Medical Therapy", chapter 31, Heart Failure/Pathogenesis and Treatment (ed: Taylor & Francis group, London, UK, pp. 557-567)



4. I am a member of numerous societies which are considered authoritative in my profession including; The Heart Failure Society of America, The International Society of Heart and Lung Transplant and the American College of Cardiology.

5. I have received awards by my peers including, numerous directorship positions of symposia and many awarded research grants.

6. A copy of my Curriculum Vitae is attached hereto as Exhibit AA@. I receive \$350.00/hour for study and \$700/hour for deposition and trial testimony.

## II. Brief Factual Summary

7. In brief summary, Ms. Vega was a 35 year old married woman with an 11 year old son when she died from heart failure and cardiogenic shock on September 28, 2008. She had no known allergies and her health history is significant for one cesarian birth in 1996 after which she was diagnosed with new-onset congestive heart failure for which she was successfully managed medically with digoxin therapy from 1996 to 2008. Prior to 2008, she had defibrillator ICD placement (2005), sleep apnea, total laparoscopic hysterectomy due to atypical hyperplasia (2007), bariatric surgery (2007) and laparoscopic cholecystectomy (2007).

### III. Documents and Materials Reviewed

8. I have reviewed the general causation expert reports and references of Dr. Marc J. Semigran and Dr. E. Don Nelson. I have also reviewed my medical chart on Ms. Vega and selected records from the St. Luke's Episcopal Hospital chart regarding Ms. Vega. I have reviewed the Kirkwood Adams article I discussed in my deposition (and the references therein) as well as various other articles referenced herein. I have also reviewed the deposition of Scottie Vega and Craig Frost and the Digoxin purchasing records for St. Luke's Episcopal Hospital, as well as various other FDA records and various records of Ms. Vega's healthcare providers, including LBJ Hospital, Memorial Hermann Hospital and Ben Taub Hospital, and various prescription records.

### IV. Expert Testimony in Previous Four Years

9. Below is a list of all my deposition and trial testimony as a retained expert during the previous four years.

DATE	CASE	TYPE OF TESTIMONY	LAW FIRM	LOCATION OF COURT
7/25/2008	<i>Arntsen v. Scott</i>	Deposition	Williamson &	146 <sup>th</sup> District Court of Bell

	<i>&amp; White, et al</i>		Rusnak	County, Texas

#### V. My Methodology

10. The methodology I used to formulate my opinions in this matter is the same methodology I use on a daily basis as a treating physician, namely, that of differential diagnosis - I reviewed the patient's clinical history and chart and available medical records, and recall records and data, along with any pertinent medical or scientific literature, and the patient's clinical presentation, and formulated an opinion as to the most probable cause of the patient's death. This methodology is routinely used by physicians in my field of practice and is generally accepted within the medical community and is the same methodology I use in my clinical practice to care for, treat and diagnose all of my patients, including my heart failure patients like Ms. Vega.

#### VI. Digoxin

11. Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart. Digoxin is a form of

digitalis, a compound in use for over 200 years, and is widely prescribed and used by millions of Americans to treat various heart conditions, including irregular heartbeats and heart failure. It is primarily used to increase cardiac contractility in patients with heart failure or to slow the ventricular rate in patients with atrial fibrillation.

12. Digitek® and digoxin are metabolized in the liver but excreted by the kidney.

Digoxin has a very narrow therapeutic range - meaning that the difference between an effective dosage and a toxic dosage is very small. Digoxin builds up in a person's body when too much digoxin is consumed. This results in Digitalis toxicity- a condition which can result in death or other serious side effects. Digitalis toxicity results when the drug, primarily excreted by the kidneys, accumulates in the blood to levels exceeding, in women, about .09 ng/ml. In fact, this study concluded that digoxin is harmful in women in serum concentration levels above 0.9 ng/ml and found that mortality in women was increased at serum concentration levels above 0.9 ng/ml.

See Georghaide M. Kirkwood F, Adams, KF et al. Digoxin in the management of cardiovascular disorders. Circulation 2004; 109:2959-2964; Lee DC-S, Johnson RA, Bingham JB et al. Heart failure in outpatients, a randomized trial of digoxin versus placebo. N Engl J Med 1982; 306:699-705; The Digitalis Investigation Group. The effect of digoxin on mortality and morbidity in patients with heart failure. N Engl J Med 1974; 81:469-474. This can occur



because of excessive dosing with too much drug ingested, decreased elimination due to kidney disease or other factors that affect the excretion of the drug, increased absorption, low levels of potassium or magnesium, acidosis, chronic lung disease, heart failure, hypothyroidism, and concomitant administration of some drugs such as amiodarone, quinidine, some antibiotics such as moxifloxacin and metronidazole., and the anti-anxiety drug, alprazolam.

13. The cardiac manifestations of digoxin toxicity include premature beats, junctional or ventricular tachycardia/fibrillation, or slow heart rates due to sinus bradycardia or AV block. Digoxin toxicity can cause a heart attack, stroke, kidney failure, nausea, vomiting, dizziness, low blood pressure, and an unstable or slow heart rate, cardiac instability and death. Generally, symptoms of digoxin toxicity include nausea, vomiting, diarrhea, loss of appetite, confusion, heart palpitations, irregular heartbeat, halos or rings of light around objects, and blind spots or blurred vision. Other symptoms include decreased urine output, excessive nighttime urination, fainting, swelling and difficulty breathing when lying down. What happens to a particular patient who suffers a toxic dose of digoxin varies from patient to patient and is dependent on that particular patient's clinical course, condition and medical history. (Heart Disease, A Textbook of Cardiovascular Medicine, Eds. Libby, Bonow, Mann, Zipes, ed 8, WB Saunders 2008, pp. 634,

784, 800).

14. Digitalis toxicity and/ or Digoxin overdose can occur from a single exposure or chronic overmedication of digitalis, or it may occur in patients with normal blood levels of digitalis if other risks are present. People with congestive heart failure are commonly given diuretics along with digoxin. Many diuretics can increase the risk of digitalis toxicity due to lower levels of potassium. Another increased risk of digitalis toxicity can occur in digitalis / digoxin patients with renal or kidney problems resulting in decreased renal function. This reduced kidney function will cause digitalis to accumulate in the body rather than being excreted normally through urine, thereby greatly increasing the chances of digitalis toxicity.

VII. Digitek®

15. Digitek® is the brand name for digoxin manufactured by Actavis. On April 25, 2008, Digitek® (digoxin tablets, all strengths) was recalled in a nationwide Class 1 recall due to defective tablets with excessive levels of digitalis. According to the recall advisory, the pills were distributed by Mylan Pharmaceuticals, Inc. under the label ABertek® and by UDL Laboratories, Inc. under the AUDL® label and were manufactured by Actavis Totowa. On April 25, 2008, the FDA posted publicly that Actavis Totowa LLC initiated the recall "due to the possibility that tablets with double the appropriate thickness have been commercially released. These tablets may contain twice the approved level of active ingredient that it appropriate (sic)." The same day Actavis issued a press release with the same warning as the FDA all-lot recall.

16. On November 14, 2008, the Department of Justice filed suit seeking a permanent injunction to bar Actavis from manufacturing and distributing generic products, including Digitek®, stating, " .....the company's release of Digoxin tablets to the market after it had discovered that some tablets from the same production batch were double thick and, thus double potent. Double dose Digoxin tablets can cause digitalis toxicity and result in cardiac instability, bradycardia and death, among other things."

17. On January 9, 2009, the FDA indicated it awaited the Court's entry of a permanent injunction that barred Actavis from manufacturing and distributing drugs ... until they came into compliance with US current good manufacturing requirements.

#### **VIII. Medical History of Mimi Rivera-Vega**

18. At the time of her death, Mimi Rivera-Vega was a 35 year old married woman with an 11 year old son. Her past medical history was significant for one cesarian birth in 1996 and HTN, obstructive sleep apnea and defibrillator ICD placement in 2005. After her son's birth in 1996, she was diagnosed with new-onset congestive heart failure for which she was successfully managed medically with a medical regimen, including digoxin therapy, from 1996 to 2008.

19. Prior to 2008, she had total laparoscopic hysterectomy due to atypical hyperplasia (2007), bariatric surgery (2007) and laparoscopic cholecystectomy (2007).

20. I began treating Mimi Vega in 2002 for management and care of her non-ischemic cardiomyopathy. While she was under my care and treatment I found Mimi to be a compliant and conscientious patient who, overall, took her medications, including digoxin, as prescribed. She was diagnosed with non-ischemic cardiomyopathy in 1996 after the birth of her son. She was effectively managed conservatively with medical therapy from the time of her diagnosis until 2008.

Ms. Vega has been on a digoxin regimen since 1996. Based on my review of her medical records, and my care and treatment of her which began in approximately June of 2002, she remained stable on medical management until January of 2008.

21. From my review of her records, Ms. Vega was first prescribed Digoxin at 0.25 mg on or about October 8, 1996 after the birth of her son. She was on Digoxin regimen when I started seeing her in June of 2002. She continued on a Digoxin regimen of 0.125 to 0.25 mg daily while under my care. From a review of her pharmacy records she filled her Digoxin (and Digitek®) prescriptions at Wal-Mart, Walgreens and Berry pharmacies. On March 10, 2008 she was discharged from St. Luke's and Dr. Bogaev prescribed her Digitek® 0.125 mg tablets with



refills for a year which she filled at Wal-Mart the following day on March 11, 2008. Hospital MAR and pharmacy records show that she received Digitek® during hospital admissions in October 2007, December 2007 through April of 2008, which is consistent with my review of hospital's purchasing records for Digoxin for 2007 and 2008 which show that for many of these months Digitek® was the only form of Digoxin tablets purchased by St. Luke's during these time periods which corroborates that she received Digitek® which was subsequently recalled by Actavis on April 25, 2008 after it had released Digitek® tablets to the market "after it had discovered that tablets from the same batch were double thick and thus double potent."

22. In October 2007, while under my care and management of her heart failure, she had right heart catheterization and placement of an IABP to gather hemodynamic data which determined that she had heart failure and severely deranged hemodynamics due to elevated pulmonary artery pressures. This did not indicate to me that her heart failure was worsening. In fact, I expected to continue to treat her as I had since 2002 – with medical management that included digoxin therapy until a transplant donor could be obtained.

23. In late January and early February 2008, Mimi "fell off the cliff" and went from being on digoxin therapy with stable congestive heart failure since 1996 to suffer worsening heart

failure which culminated in cardiogenic shock which resulted in three LVAD placements, bi-lateral leg amputations, and ultimately, death on September 20, 2008.

24. In February 2008 she had an LVAD placed to treat her cardiogenic shock. I had hoped to primarily transplant Ms. Vega and she was on a transplant list. However, it became necessary to implant an LVAD to treat her cardiogenic shock. After receiving the LVAD she developed right heart failure which led to aortic root thrombosis and the placement of a second LVAD.

25. In looking at her total clinical presentation, based on her medical history, her medical chart, and my care and treatment of her, I believe she ingested excess level of the active ingredient of digoxin that was the subject of the nationwide recall and the FDA inspections that found that Actavis released to the market Digoxin tablets that were double thick and double potent. This is based on the totality of her clinical presentation. There is no other medically significant explanation for her dramatic decline and ultimate death. That I did not see any markedly elevated serum digoxin concentration levels between February 2008 and April 24, 2008. I would not have expected to see any markedly elevated serum digoxin concentration levels during this time period because she had the LVAD during that period of time. The LVAD

gets rid of heart failure and her serum blood levels would be affected because the LVAD increases renal perfusion beyond baseline. Therefore, if Ms. Vega was ingesting digoxin with elevated levels of the active ingredient post LVAD placement, the increased renal perfusion would have prevented her from having elevated levels and clinical signs of digoxin toxicity. Digoxin toxicity causes progressive worsening of heart failure, culminating in cardiogenic shock. In other words, it takes whatever reserves a heart failure patient has left and causes them to go over the cliff. With Mimi, digoxin toxicity caused her heart failure to become progressively worse, culminating in cardiogenic shock and death.

#### Summary of Relevant Events

26. An abbreviated summary of relevant portions of Ms. Vega's medical history is summarized below:

09/30/1996	Cesarian birth of son at LBJ Hospital
10/14/1996	Diagnosis of heart failure with EF of 15-20% - started on digoxin .25mg and discharged from Ben Taub Hospital with diagnosis of post-partum cardiomyopathy - on digoxin therapy. <u>Current Medications:</u> Monopril 20 mg QD; Lasix 40 mg QD; Digoxin 0.25 mg QD; K-Dur 10 mEq BID; Multivitamin QD.
01/29/1997	Discharged from LBJ Cardiology Clinic. <u>Current Medications:</u> Monopril 20

mg QD; Lasix 40 mg QD; FeSoq 325 mg QD; Digoxin 0.25 mg QD; K-Dur 10 mEq BID; Multivitamin.

06/19/2002 Right and left heart catheterization and coronary angiogram for CHF exacerbation – negative for coronary artery disease. Current Medications: Lasix 40mg BID; K-Dur 10mEq QD; Spironolactone 25 mg QD; Digoxin 0.125 mg QD; Prinivil 5 mg BID; Tequin 400 mg QD x 10 days; Robitussin AC 10cc p.r.n. cough.

01/27/2005 Pacemaker ICD placement by Dr. John Seger at St. Luke's Episcopal Hospital due to dilated cardiomyopathy. Current Medications: Lasix 40mg BID; Lipitor 10mg BID; Spironolactone 25 mg QD; Digoxin 0.125 mg QD; Lisinopril 20 mg QD; Coreg 6.25 mg BID; Potassium 10 mEq QD; Xenical 120 mg TID; Coumadin 5 mg QD; Aspirin one QD.

05/17/2005 Diagnosed with obstructive sleep apnea at St. Luke's Sleep Center. Current Medications: Lasix; Lipitor; Spironolactone; Digoxin; Lisinopril; Coreg; Potassium; Coumadin; Aspirin.

03/19/2007 Lap band surgery at Memorial Hermann by Dr. Terry Scarborough. Current Medications: Lasix 40mg BID; Lipitor 10mg BID; Spironolactone 25 mg QD; Digoxin 0.125 mg QD; Lisinopril 20 mg QD; Potassium 10 mEq QD; Coumadin 5 mg QD; Chewable MBI – 60 tablets QD; Chewable Calcium Citrate 500 mg – 60 tablets BID; Loritab elixir – 15-30 QD – dispensed 500 ml; Usodeoxycholic acid 300mg BID – dispensed 60; Colace elixir – dispensed 600 ml – 10 ml QD; Prevacid 30 mg – QD – dispensed 30.

07/14/2007 Admitted to Memorial Hermann to Dr. Terry Scarborough with abdominal pain.

07/17/2007 Laparoscopic cholecystectomy by Dr. Terry Scarborough

07/17/2007 Discharged from Memorial Hermann with diagnosis of endometrial cancer,



CHF and Cholecystitis. Underwent cholecystectomy. Current Medications:  
Lasix 40mg BID; Spironolactone 25 mg QD; Digoxin; Lisinopril 10 mg QD;  
Potassium.

07/30/2007 Admitted to St. Luke's with complaints of nausea, vomiting and chest pain  
suffered ventricular tachycardia during admission and jaundice.

07/30/2007 Digoxin level of 0.1 ng/ml

08/03/2007 Digoxin level of 3.2 ng/ml

08/03/2007 Discharged from St. Luke's. Current Medications: Lasix 40mg twice a day;  
Spironolactone 25 mg daily; Digoxin; Lisinopril 5 mg at bedtime; Potassium  
Chloride 20 mEq every day; Coreg 3.125 mg BID; Demadex 20 mg BID;  
Protonix 40 mg daily.

08/19/2007 Admitted to St. Luke's for volume overload.

08/21/2007 Digoxin level of 0.1 ng/ml

08/23/2007 Discharged from St. Luke's. Current Medications: Lasix 40mg BID;  
Spironolactone 25 mg QD; Lisinopril 5 mg at bedtime; Potassium 20 mEq  
QD; Carvedilol 6.25 mg q 12 hrs.

09/04/2007 Admitted to St. Luke's

09/12/2007 Total laparoscopic hysterectomy by Dr. Frumovitz

09/14/2007 Discharged from St. Luke's. Current Medications:

10/18/2007 Admitted to St. Luke's

10/27/2007 Discharged from St. Luke's

11/13/2007 Admitted to St. Luke's

11/17/2007 Discharged from St. Luke's

01/22/2008 Admitted to St. Luke's with complaints of SOB, nausea and vomiting.

01/23/2008 Digoxin level of 1.2 ng/ML

01/25/2008 Prescription for Digoxin 0.25 mg tablet every day -- 90 tablets with 3 refills  
-- by Dr. Delgado

01/25/2008 Discharged from St. Luke's. Current Medications: Lasix 80 mg BID;  
Alprazolam 25 mg every 8 hours; Digoxin .25 mg daily; Carvedilol 3.125  
mg BID; Lisinopril 2.5 mg daily; Metolazone 5 mg daily; Protonix 40 mg  
daily; Amiodarone 100 mg daily; Potassium chloride 20 mEq BID.

01/31/2008 Admitted to St. Luke's for SOB, nausea, vomiting and weakness.

02/05/2008 Right and Left Cath by Dr. Delgado, insertion of intra-aortic balloon pump

02/05/2008 Mimi found to be acceptable candidate for heart transplant

02/11/2008 Insertion of LVAD (Jarvik 2000) via L thoracotomy and removal of balloon  
pump

02/13/2008 Redo left thoractomy and evacuation of left chest hematoma by Dr. Frazier

02/28/2008 Digoxin level of 1.2 ng/ML

03/10/2008 Discharged from St. Luke's. Current Medications: Aspirin 81 mg daily;  
Carvedilol 3.125 mg every 12 hours; Dipyridamole 75 mg TID; Digoxin  
0.125 mg daily; Mag oxide 400 mg daily; Ramipril 7.5 mg daily; Colace  
100 mg BID; Coumadin 65 mg daily.

03/11/2008 Digitek® 0.125 mg prescription filled at Wal-Mart.

03/17/2008 Admitted to St. Luke's with complaints of SOB, edema, and fatigue

04/04/2008 Discharged from St. Luke's. Current Medications: Chlorhexadine gluconate  
0.12% 15 ml orally 3 times a day; Eplerenone 25 mg daily; Carvedilol  
3.125 mg twice a day with meals; Aspirin 81 mg daily; Dipyridamole 75 mg  
every 8 hours; Digoxin 0.125 mg daily; Ramipril 5 mg daily; Torsemide 40  
mg daily; Coumadin 7.5 mg daily; Lovenox 80 mg subcu twice daily.

04/22/2008 Admitted to St. Luke's for right leg pain

4/25/2008	Discharged with prescription for Digoxin 0.125 mg tablet #30 with 3 refills by Dr. Loyalka
04/25/2008	Discharged from St. Luke's. <u>Current Medications:</u> Digoxin 0.125 mg daily; Coumadin 16 mg daily; Carvedilol 3.125 mg twice a day; Aspirin 81 mg daily; Persantine 75 mg PID; Ramipril 5mg daily; Toursemid 40 mg daily; Eplerenone 25 mg daily.
4/25/2008	FDA posted Actavis Totowa LLC All-Lot Recall of Digitek®
05/17/2008	Final admission to St. Luke's for chest pain and SOB.
05/18/2008	Exchange of Jarvik 2000 LVAD device by Dr. Gregoric
05/23/2008	Right and left heart catheterization
05/27/2008	Exchange of Jarvik LVAD device to HM II and placement of Levitronix RVAD – thrombus of ascending aorta
06/03/2008	Exchange of Levitronix RVAD device to AB 5000
06/20/2008	Tracheostomy
07/09/2008	Exchange of HM II LVAD device to AB 5000 by Dr. Frazier; Clots in right tracheobronchial tree; pulmonary insufficiency
08/19/2008	Bilateral below-the-knee amputations by Dr. Frazier
09/02/2008	Orthotopic heart transplantation
09/22/2008	Repair of bronchopleural fistula on both sides, right and left, cardiac muscle biopsy
09/28/2008	Cardiac muscle biopsy; revision of bronchopleural fistula repairs.
09/28/2008	Death – Death Certificate lists CHF and Cardiomyopathy

**V. Summary of Opinions**

27. Based on my review of the medical records, medical literature, depositions, my education, training and experience, and my clinical experience, it is my opinion, based on a reasonable degree of medical probability that a substantial factor and proximate cause of Mimi

Rivera-Vega's death was caused by digoxin toxicity brought on by her ingestion of Digitek® which has been shown to have varying pill dosages. She was particularly vulnerable due to her long history of heart failure. It is well known among the medical community that digoxin levels are an imperfect tool in measuring digoxin toxicity – rather, digoxin toxicity is a clinical diagnosis based on the patient's entire clinical course and presentation. Additionally, the presence of ischemic heart disease and acidosis can lead to toxic effects at lower levels. I base my diagnosis of digoxin toxicity on Ms. Vega's clinical presentation and the highly abnormal EKG rhythms recorded on the telemetry monitor. My clinical diagnosis based on her clinical presentation is that she ingested Digitek® (digoxin) tablets which caused her to suffer symptoms of digitalis toxicity, cardiogenic shock and death. It is my opinion, based on a reasonable degree of medical probability, that Mimi Rivera-Vega's ingestion of excess levels of Digitek® (Digoxin) caused progressive worsening of heart failure which culminated in cardiogenic shock and death.

28. In my opinion, the cause of death of Ms. Vega was progressive heart failure and cardiogenic shock due to digoxin toxicity from a known Digitek® product defect which was known at approximately that time period and which necessitated a product recall and was the cause of death of other individuals. Review of Ms. Vega's clinical history and review of the history of the Digitek® product recall and the scientific literature indicates that the levels attained by Ms. Vega were in the range of the fatalities caused by this improperly manufactured product.

29. Knowing now that Actavis issued an all-lot recall of Digitek® in April of 2008 and



that the FDA found improperly manufactured Digitek® products at the Actavis facility that had twice the appropriate level of the active ingredient that were released to the marketplace, and knowing that Ms. Vega ingested Digitek in late 2007 and January and February of 2008, when she suddenly “fell off the cliff”, it follows that the primary incident triggering the various events prior to Ms. Vega’s death was digoxin toxicity and it is my opinion that the progressive worsening of her heart failure and resultant cardiogenic shock and death was due to digoxin toxicity. It was digoxin toxicity that triggered the instability in her previously stable heart failure.

30. I do not believe her death was due to any of the following factors which may lead to or contribute to digoxin toxicity.

amiodarone therapy (reduces renal and nonrenal clearance of digoxin and may have additive effects on the heart rate);

Carvedilol (may increase digoxin blood levels in addition to additive effects on slowing heart rate);

30. In summary, I believe the cause of death of Ms. Vega was digoxin toxicity due to improperly manufactured Digitek® tablets which caused progressive heart failure and cardiogenic shock and ultimately death. I believe, based upon a reasonable degree of medical probability,

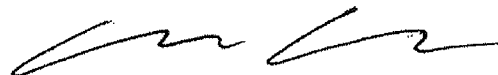
that Mimi Vega would have recovered and led a normal life if she had not had the digoxin toxicity.

I had submitted Ms. Vega to the Medical Review Board for candidacy for a heart transplant and on February 5, 2008 her case was evaluated by the Medical Review Board and she was found to be a medically acceptable candidate for a heart transplant and was placed on the active list to await a suitable donor, and received an orthotic heart transplant on September 2, 2008.

31. Therefore, it is my opinion, to a reasonably degree of medical probability, that Mimi Rivera-Vega suffered digoxin toxicity caused by the recalled Digitek® pills she received and ingested from October of 2007 through April 2008 that led to a cascade of events that caused her heart failure to progressively worsen culminating in cardiogenic shock and death.

32. This Report represents my medical, scientific and professional opinions to a reasonable degree of medical certainty and probability. I reserve the right to supplement this Report as additional information becomes available.

Sincerely,

A handwritten signature in black ink, appearing to read 'Reynolds Delgado', with a stylized, flowing script.

Reynolds Delgado, M.D.

**CURRICULUM VITAE**  
Reynolds M. Delgado III, M.D., F.A.C.C.

**BUSINESS ADDRESS**

6624 Fannin, Suite 1910  
Houston, Texas 77030  
Tel: (713) 383-9300  
Fax: (713) 383-8306

**EDUCATION**

Undergraduate

Bachelor of Arts in Biology, University of Texas at Austin, Texas, June 1987

Post Graduate

Doctor of Medicine, University of Texas Southwestern Medical School, Dallas, Texas,  
June 1991

**POST-GRADUATE MEDICAL EDUCATION**

Residency

Internal Medicine, University of Texas Southwestern Medical Center, Dallas, July 1991 -  
June 1994

Fellowship

Cardiology, University of Texas Health Science Center, Houston, June 1994 - June 1997  
Including a fifteen month fellowship in Heart Failure and Cardiac Transplantation at UT  
and Texas Heart Institute/St. Luke's Episcopal Hospital

Appointments

Chief Fellow/Junior Faculty, Research and Clinical Cardiac Transplantation and Heart  
Failure, Texas Heart Institute, Houston, December 1996 - June 1997

**PROFESSIONAL EXPERIENCE**

Private Practice Cardiologist with Cardiology Consultants of Houston, July 1997-October  
1999

Private Practice Cardiologist and Principal of Delgado Cardiovascular Associates,  
October 1999-present

Heart Failure and Transplantation Cardiologist, St. Luke's Episcopal Hospital/Texas  
Heart Institute, Basic Science Researcher in Heart Failure, Texas Heart Institute, Baylor  
College of Medicine and UT Houston Medical School, July 1997-present

Director, Institute for Heart Failure Treatment and Research, December 2001 - present

Medical Director, Mechanical Support Devices in Heart Failure, Texas Heart Institute,  
May 2003 - present

MIMI VEGA 01551



Reynolds M. Delgado III, MD, FACC  
Page 1  
10/19/2009



#### **LICENSURE AND BOARD CERTIFICATION**

Texas Medical License held  
Board Certified, American Board of Internal Medicine, September 1994  
Board Certified, American Board of Internal Medicine, Cardiovascular Diseases,  
November 1997, re-certified November 2008

#### **ACADEMIC AND HOSPITAL APPOINTMENTS**

Clinical Assistant Professor of Medicine, Baylor College of Medicine, July 2000 –  
present

Clinical Assistant Professor of Medicine, University of Texas Health Science Center  
Houston, January 2002 – present

Professional Staff, St. Luke's Episcopal Hospital, 1998 – present

Medical Staff Member, Texas Heart Institute, 1998 - present

#### **COMMITTEE MEMBERSHIPS**

Institutional Review Board, St. Luke's Episcopal Hospital, 1998 - present

Transplant Medical Review Board, St. Luke's Episcopal Hospital, 1998 – present

Scientific Council on Mechanical Circulatory Support, International Society for Heart  
and Lung Transplantation, 2000-Present

Roderick MacDonald Fund Philanthropic Research Committee, 2000 – present

Steering Committee, ADVANCENT, The National Registry to Advance Heart Failure,  
2002 - present

Heart Failure Advisory Board, Guidant Corporation, August 2003 - present

Medical Advisory Board, Thoratec Corporation, August 2003 – present

Medical Advisory Board, Medtronic Corporation, July 2004-present

Medical Education Committee, Texas Heart Institute, January 2004 – present

President, Inter-American Heart Failure Society, January 2007- present

#### **EDITORIAL BOARD**

Reviewer, *Circulation*, 1998 - present

Reviewer, *Journal of Heart Lung Transplantation*, 1999 - present

Reviewer, *Texas Heart Institute Journal*, 2000 – present

Reviewer, *Congestive Heart Failure*, 2002 - present

Editorial Board Member, *Texas Heart Institute Journal*, 2003 - present

MIMI VEGA 01552

Reynolds M. Delgado III, MD, FACC

Page 2

10/19/2009

Editorial Board Member, *Congestive Heart Failure*, 2004

#### PROFESSIONAL SOCIETIES

American Heart Association

International Society of Heart & Lung Transplantation

Heart Failure Society of America

American College of Cardiology, Fellow

American Society of Artificial Internal Organs

Houston Cardiology Society, Executive Committee

American Society of Nuclear Cardiology

American Society of Transplant Physicians

American Medical Association

Texas Medical Association

Harris County Medical Society

#### PUBLICATIONS

##### Abstracts

1. **Delgado III RM**, Willerson JT. Pathophysiology of heart failure: a look at the future. *Tex Heart Inst J* 1999;26(1):28-33.

2. Ozenne A, Merten M, **Delgado III RM**. Safety and diagnostic accuracy of adenosine 99m-Tc tetrofosmin SPECT imaging with a 4 minute infusion protocol. *Journal of Nuclear Cardiology* 1999;6:568.

3. **Delgado III RM**, Eastwood CA, Nawar MA. Clinical experience with continuous home milrinone combined with beta blocker therapy in severe congestive heart failure. *Journal of Cardiac Failure* 1999 Sept;5(3):60.

4. Torre-Amione G, Stetson SJ, Youker KA, Durand JB, Radovancevic B, **Delgado III RM**, Frazier OH, Entman ML, Noon GP. Decreased expression of tumor necrosis factor- $\alpha$  in failing human myocardium after mechanical circulatory support: A potential mechanism for cardiac recovery. *Circulation* 1999 Sept 14; 100(11):1189-93

5. **Delgado III RM**, Nawar MA, McKay K, Costas GG, Vaughn W, Willerson JT. Improvement in left ventricular systolic function with a cyclooxygenase inhibitor in a murine adriamycin heart failure model. *Circulation* 1999 Nov 2;100(18):I-122.

6. Eastwood CA, Donaho EK, Hudkins JL, **Delgado III RM**, Travis L. Implementation and outcomes of a hospital-based heart failure program to support private practice cardiologists. *Journal of Cardiac Failure* 2000 Sept;6(3):70.

7. Eastwood CA, Hudkins JL, Donaho EK, **Delgado III RM**. Continuous home intravenous milrinone for severe heart failure: nursing care and outcomes. *Journal of Cardiac Failure* 2000 Sept;6(3):71.

8. **Delgado III RM**, Razeghi P, Radovancevic B. Difficult cases in heart failure: Effective treatment of severe acute myocarditis with intravenous immune globulin and pulse corticosteroids in a 32 year old patient. *Congest Heart Fail* 2000 Sept;6(5):277-279.

MIMI VEGA 01553

Reynolds M. Delgado III, MD, FACC

Page 3

10/19/2009



9. **Delgado III RM**, Eastwood CA, Jax T. Successful weaning from milrinone of a patient with severe congestive heart failure using carvedilol. *Congest Heart Fail* 2001 Jan;7(1):47-50.
10. Frazier OH, Gregoric ID, **Delgado III RM**, Myers TJ, Radovancevic B, Khan T, Miller K, Ho JK, Jarvik RK. Initial experience with the Jarvik 2000 left ventricular assist system as a bridge to transplantation: report of 4 cases. *J Heart Lung Transplant* 2001 Feb;20(2):201.
11. Khan T, Okerberg K, Hernandez A, Miller K, Myers TJ, Radovancevic B, **Delgado III RM**, Gregoric ID, Frazier OH. Assessment of myocardial recovery using dobutamine stress echocardiography in LVAD patients. *J Heart Lung Transplant* 2001 Feb;20(2):202-203.
12. **Delgado III RM**, Myers TJ, Radovancevic B, Gregoric ID, Miller K, Khan T, Majano R, Kar B, Jarvik RK, Frazier OH. First clinical use of the Jarvik 2000 as a bridge to transplantation: hemodynamic effects. *ASAIO J* 47(2):135, 2001.
13. **Delgado III RM**, Radovancevic B, Zewail A, Myers TJ, Frazier OH, Jarvik RK. Use of the Jarvik 2000 Left Ventricular Assist System as a bridge to transplantation: a report of the first 10 cases. *Journal of Cardiac Failure* Sept 2001;7(3)(Supp 2):39.
14. **Delgado III RM**, Myers TJ, Radovancevic B, Gregoric ID, Khan T, Miller K, Jarvik RK, Frazier OH. Effects of prolonged partial pulsatile flow in patients treated with the Jarvik 2000 Ventricular Assist Device. *Circulation* Oct 23, 2001; 104(17)(Supp II):441.
15. **Delgado III RM**, Myers TJ, Scroggins N, Frazier OH. The unique physiology of the Abicor Total Artificial Heart in the patient with severe congestive heart failure. *ASAIO J* Mar-Apr 2002; 48(2):165.
16. Miller KA, **Delgado III RM**, Myers TJ, Khan T, Gregoric ID, Frazier OH. Quality of life assessment in patients with the Jarvik 2000 Ventricular Assist Device and bridged to transplant. *ASAIO J* Mar-Apr 2002; 48(2):140.
17. Frazier OH, **Delgado III RM**, Gregoric ID, Myers T, Moser R, Wadia Y, Kar B, Letsou G, Messner G, Harting MT, Radovancevic B. Ascending versus descending aorta anastomosis with the Jarvik 2000 LVAS. *ASAIO J* 2003; 49(2):166.
18. Khan T, **Delgado III RM**, Radovancevic B, Torre-Amione G, Abrams J, Miller K, Myers T, Okerberg K, Stetson SJ, Gregoric I, Hernandez A, Frazier OH. Dobutamine stress echocardiography predicts myocardial improvement in patients supported by left ventricular assist devices (LVADs): hemodynamic and histologic evidence of improvement before LVAD explantation. *J Heart Lung Transplant* 2003 Feb;22(2):137-46.

MIMI VEGA 01554

Reynolds M. Delgado III, MD, FACC  
Page 4  
10/19/2009

19. Zewail Am, Nawar M, Vrtovec B, Eastwood C, Kar MN, **Delgado III RM**. Intravenous milrinone in treatment of advanced congestive heart failure. *Tex Heart Inst J* 2003;30(2):109-13.
20. **Delgado III RM**. The future of mechanical circulatory support. *Curr Opin Cardiol* 2003 May;18(3):199-209.
21. **Delgado III RM**, Radovancevic B, Thomas CD, Kar B, Radovancevic R, Torre-Amione G, Frazier OH. Evaluation of reversibility of pulmonary hypertension in heart transplant candidates. *Circulation* 2003; 108(17):IV-426.
22. Zewail A, Broom, Eastwood C, Scroggins N, Kar B, Wadia Y, **Delgado III RM**. Use of systolic time ratio and B-type natriuretic peptide to predict mortality in patients with heart failure. *J Cardiac Failure* 2003; 9 (5-Suppl 1): S105.
23. **Delgado III RM**, Radovancevic B, Vrtovec B, Radovancevic R, Thomas CD, Kar B, Frazier OH. Perioperative use of nesiritide in heart failure patients undergoing implantation of left ventricular assist device. *J Cardiac Failure* 2003; 9 (5-Suppl 1): S111.
24. **Delgado III RM**, DeMarco T, Agocha G. Rationale and methodology of a national registry for patients with left ventricular dysfunction: the ADVANCENT project. *J Cardiac Failure* 2003; 9 (5-Suppl 1): S111
25. Frazier OH, **Delgado III RM**. Mechanical circulatory support for advanced heart failure: where does it stand in 2003? *Circulation* 2003 Dec 23;108(25):3064-8.
26. Kar B, Civitello A, Gregoric ID, Radovancevic B, Gemmato C, Myers TJ, **Delgado III RM**, Frazier OH. High-risk coronary interventions involving percutaneous left ventricular support. *J Heart Lung Trans* Feb 2004; 23(2S):85-86.
27. Wadia Y, **Delgado III R M**, Allison P, Vaughn WK, Kar B, Messner G, Myers T, Robertson K, Gregoric ID, Patel V, Frazier OH. Heparin induced thrombocytopenia in patients with an axial flow left ventricular assist device. *J Heart Lung Trans* Feb 2004;23(2S):109
28. **Delgado III RM**, Nawar MA, Zewail AM, Kar B, Vaughn WK, Wu KK, Aleksic N, Sivasubramanian N, McKay K, Mann DL, Willerson JT. Cyclooxygenase-2 inhibitor treatment improves left ventricular function and mortality in a murine model of doxorubicin-induced heart failure. *Circulation* 2004 Mar 23;109(11):1428-33.
29. **Delgado III RM**, Poulin GV, Vrtovec B, Eastwood C, Radovancevic B, Franklin W, Kar B, Schlegel TT. The utility of high frequency QRS electrocardiogram in the diagnosis of cardiomyopathy. *J Amer Coll Car*, Mar 2004;43(5A):17A

MIMI VEGA 01555

Reynolds M. Delgado III, MD, FACC  
Page 5  
10/19/2009

30. Kar B, Frazier OH, Myers TJ, **Delgado III RM**, Wadia Y, Scroggins N, Gregoric ID, Radovancevic B. Effect of nesiritide on renal function after implantation of the AbioCor Total Artificial Heart. *J Amer Coll Card* Mar 2004;43(5A):208-9A
31. Kar, B, Butkevich A, Civitello AB, Nawar MA, Walton B, Messner GN, Gregoric ID, Feldman J, Myers TJ, Gemmato C, **Delgado III RM**. Hemodynamic support with a percutaneous left ventricular assist device during stenting of an unprotected left main coronary artery. *Tex Heart Inst J* 2004;31(1):84-6.
32. Frazier OH, **Delgado III RM**, Scroggins N, Odegaard P, Kar B. Mechanical bridging to improvement in severe acute "nonischemic, nonmyocarditis" heart failure. *Congest Heart Fail* 2004 Mar-Apr;10(2):109-13.
33. Frazier OH, **Delgado III RM**, Kar B, Patel V, Gregoric ID, Myers TJ. First clinical use of the redesigned HeartMate II left ventricular assist system in the United States: a case report. *Tex Heart Inst J*. 2004;31(2):157-9. Erratum in: *Tex Heart Inst J* 2004;31(3):333.
34. Wadia Y, **Delgado III RM**, Odegaard P, Frazier OH. Jarvic 2000 FlowMaker axial-flow left ventricular assist device support for management of refractory ventricular arrhythmias. *Congest Heart Fail* 2004 Jul-Aug;10(4):195-6.
35. Miller K, Myers TJ, Robertson K, Shah N, **Delgado III RM**, Gregoric ID. Quality of life in bridge-to-transplant patients with chronic heart failure after implantation of an axial flow ventricular assist device. *Congest Heart Fail* 2004 Sep-Oct;10(5):226-9.
36. Amir O, Kar B, **Delgado III RM**, Younis AG, Gregoric ID, Smart FW, Radovancevic B, Frazier OH. Images in cardiovascular medicine. High left ventricular assist device flows resulting from combined native aortic valve and outflow valve regurgitation. *Circulation* 2005 Feb 1;111(4):e34.
37. Amir, O, **Delgado III RM**, Kar B, Gregoric ID, Radovancevic B, Smart F, Cohn W. Recovery from multi-organ failure in a patient with a continuous-flow left ventricular assist device. *J Heart Lung Transplant* 2005 Aug;24(8):1128-9.
38. Kar B, **Delgado III RM**, Radovancevic B, Myers TJ, Wadia Y, Letsou GV, Riaz I, Metcalfe R, Gregoric I, Harting MT. Vascular thrombosis during support with continuous flow ventricular assist devices: correlation with computerized flow simulations. *Congest Heart Fail* 2005 Jul-Aug;11(4):182-7.
39. **Delgado III RM**, Bergheim M. Management of acute and chronic heart failure with left ventricular assist devices. *Am Heart Hosp J* 2005 Summer;3(3):153-60.
40. Albrecht CA, Giesler GM, Kar B, Hariharan R, **Delgado III RM**. Intravenous milrinone infusion improves congestive heart failure caused by diastolic dysfunction: a brief case series. *Tex Heart Inst J* 2005;32(2):220-3.

Reynolds M. Delgado III, MD, FACC  
Page 6  
10/19/2009

MIMI VEGA 01556



41. Kar B, **Delgado III RM**, Civitello AB, Loyalka P, Paniagua D, Fish RD, Forrester MD, Moser D, Radovancevic B. Temporary support with Tandemheart pVAD during percutaneous aortic valve replacement in an animal model: rationale and methodology. *Tex Heart Inst J* 2005;32(3):283-6.
42. Kar B, **Delgado III RM**, Frazier OH, Gregoric ID, Harting MT, Wadia Y, Myers TJ, Moser RD, Freund J. The effect of LVAD aortic outflow-graft placement on hemodynamics and flow: Implantation technique and computer flow modeling. *Tex Heart Inst J* 2005;32(3):294-8.
43. Amir O, Bracey AW, Smart FW, **Delgado III RM**, Shah N, Kar B. A successful anticoagulation protocol for the first HeartMate II implantation in the United States. *Tex Heart Inst J* 2005;32(3):399-401.
44. Gregoric ID, Nolen MT, Ksela J, Chandler LB, Messner GN, Cervera RD, Smart FW, **Delgado III RM**, Frazier OH. Posttransplant off-pump coronary bypass and laser revascularization in a Jehovah's Witness. *Tex Heart Inst J* 2005;32(3):434-6.
45. Amir O, **Delgado III RM**, Kar B, Gregoric ID, Radovancevic B, Smart F, Cohn W. Recovery from multi-organ failure in a patient with a continuous-flow left ventricular assist device. *J Heart Lung Transplant* 2006 Jan;25(1):148.
46. Amir O, Radovancevic B, **Delgado III RM**, Kar B, Radovancevic R, Henderson M, Cohn WE, Smart FW. Peripheral vascular reactivity in patients with pulsatile vs axial flow left ventricular assist device support. *J Heart Lung Transplant* 2006 Apr;25(4):391-4.
47. Letsou GV, Connelly JH, **Delgado III RM**, Myers TJ, Gregoric ID, Smart FW, Frazier OH. Is native aortic valve commissural fusion in patients with long-term left ventricular assist devices associated with clinically important aortic insufficiency? *J Heart Lung Transplant* 2006 Apr;25(4):395-9.
48. Letsou GV, Sdringola S, Gregoric ID, Patel V, Myers TJ, **Delgado III RM**, Frazier OH. Myocardial perfusion as assessed by positron emission tomography during long-term mechanical circulatory support. *Congest Heart Fail* 2006 Mar-Apr;12(2):69-74.
49. Kar B, Adkins LE, Civitello AB, Loyalka P, Palanichamy N, Gemmato CJ, Myers TJ, Gregoric ID, **Delgado III RM**. Clinical experience with the TandemHeart percutaneous ventricular assist device. *Tex Heart Inst J* 2006;33(2):111-5.
50. Amir O, Kar B, Civitello AB, Palanichamy N, Shakir A, **Delgado III RM**. Unprotected left main stent placement in a patient with Takayasu's arteritis: an unusual solution for an unusual disease. *Tex Heart Inst J* 2006;33(2):253-5.

MIMI VEGA 01557

Reynolds M. Delgado III, MD, FACC  
Page 7  
10/19/2009

51. **Delgado III RM**, Palanichamy N, Radovancevic R, Vrtovec B, Radovancevic B. Brain natriuretic peptide levels and response to cardiac resynchronization therapy in heart failure patients. *Congest Heart Fail* 2006 Sep-Oct;12(5):250-3.
52. **Delgado III RM**, Nawar M, Loghin C, Myers TJ, Gregoric ID, Pool T, Scroggins N, Radovancevic B, Frazier OH. Catheterization of the AbioCor implantable replacement heart: evaluation of the unique physiology created by the device. *Tex Heart Inst J* 2006;33(3):359-60.
53. **Delgado III RM**, Radovancevic R, van Rossem CC, Gaemers SJ, Castanes S, Adams SC, Bracey AW, Radovancevic B. The effect of administering erythropoiesis-stimulating proteins in patients with chronic heart failure: results from a retrospective study. *Congest Heart Fail* 2006 Nov-Dec;12(6):297-301.
54. Gemmato C, Radovancevic B, Carranza S, Radovancevic R., **Delgado III RM**, Gregoric ID, Frazier OH. Improved Quality of Life and Functional Improvement in Patients Supported with the Heartmate II, an Axial Flow Left Ventricular Assist Device. *J of Heart Lung Trans* Feb 2007;26(2):284.
55. Vrtovec B, Radovancevic B, **Delgado III RM**, Radovancevic R, Bracey AW, Gregoric ID, Frazier OH. Significance of Anemia in Patients Undergoing Long-Term LVAD Support. *J of Heart Lung Trans* Feb 2007;26(2):88.
56. Chandra D, Kar B, Idelchik G, Simpson L, Loyalka P, Gregoric ID, **Delgado III RM**, Frazier OH. Usefulness of percutaneous left ventricular assist device as a bridge to recovery from myocarditis. *Am J Cardiol* 2007 Jun 15;99(12):1755-6.
57. **Delgado III RM**, Radovancevic B. Symptomatic relief: left ventricular assist devices versus resynchronizaton therapy. *Heart Fail Clin* 2007;3(3):259-65.
58. Miller LW, Pagani FD, Russell SD, John R, Boyle AJ, Aaronson KD, Conte JV, Naka Y, Mancini D, **Delgado III RM**, MacFillivray TE, Farrar DJ, Fraizer OH; HeartMate II Clinical Investigators. Use of a continuous-flow device in patients awaiting heart transplantation. *N Engl J Med* 2007 Aug 30;357(9):885-96.
59. Greenberg B, Czerska B, Abraham WT, Neaton JD, **Delgado III RM**, Mather P, Bourge R, Parker IC, Konstam MA, MOMENTUM Investigators and Coordinators. Rationale, design, and methods for a pivotal randomized clinical trial of continuous aortic flow augmentation in patients with exacerbation of heart failure: the MOMENTUM trial. *J Card Fail* 2007 Nov;13(9):715-21.
60. Amany, A., **Delgado III RM**. Impedance Cardiography demonstrates Cardiac Output and Cardiac Index values that are significantly greater than similar measurements done through Cardiac Catheterization. *Heart Failure Society of America* 2007

MIMI VEGA 01558

Reynolds M. Delgado III, MD, FACC  
Page 8  
10/19/2009



61. Munir SM, Bogaev RC, Sobash E, Shankar KJ, Gondi S, Stupin IV, Robertson J, Brewer MA, Casscells SW, **Delgado III RM**, Ahmed A. Devices in heart failure: potential methods for device-based monitoring of congestive heart failure. *Tex Heart Inst J* 2008;35(2):166-73.
62. Brukner BA, Jacob LP, **Delgado III RM**, Reardon MJ, Loebe M, Gregoric ID, Bogaev RC, Torre-Amione G, Frazier OH. Reversal of secondary pulmonary hypertension in patients supported by left ventricular assist devices. Supplement to the *J of Heart Lung Trans* Feb 2008;27(2S):S185-186.
63. Conte JV, Miller LW, Pagani FD, Russell SD, Aaronson KD, John R, Boyle AJ, Naka Y, Mancini D, **Delgado III RM**, MacGillivray TE, Farrar DJ, Frazier OH. One year followup with a continuous flow LVAD as a bridge to heart transplant. Supplement to the *J of Heart Lung Trans* Feb 2008;27(2S):S244-5.
64. Greenberg B, Czerska B, **Delgado III RM**, Bourge R, Zile MR, Silver M, Klapholz M, Haeusslein E, Mehra MR, Mather P, Abraham WT, Neaton JD, Brown BS, Parker IC, Konstam MA; MOMENTUM Investigators and Coordinators. Effects of continuous aortic flow augmentation in patients with exacerbation of heart failure inadequately responsive to medical therapy: results of the Multicenter Trial of the Orqis Medical Cancion System for the Enhanced Treatment of Heart Failure Unresponsive to Medical Therapy (MOMENTUM). *Circulation* 2008 Sep 16;118(12):1241-9.
65. Herlihy JP, Loyalka P, Gnananandh J, Gregoric ID, Dahlberg CG, Kar B, **Delgado III RM**. PleurX catheter for the management of refractory pleural effusions in congestive heart failure. *Tex Heart Inst J* 2009;36(1):38-43.
66. Amir O, **Delgado III RM**, Kar B, Smart FW. The value of cardiac magnetic resonance imaging in the diagnosis of isolated non-compaction of the left ventricle. *Isr Med Assoc J* 2009 May;11(5):313-4.
67. **Delgado III RM**. ACC-AHA Heart Transplant Guidelines 2010.

Manuscripts

1. **Delgado III RM**, Fink M, Brown Jr RM. Imaging of sub-micron objects with the light microscope. *J of Microscopy* 1989;154(2):129-141.
2. Frazier OH, Benedict CR, Radovancevic B, Bick RJ, Capek P, Springer WE, Marcis MP, **Delgado III RM**. Improved left ventricular function after chronic left ventricular unloading. *Ann Thorac Surg* 1996;62(3):675-81.
3. **Delgado III RM**, Massin EK. Congestive heart failure: when to consider new therapies. *Managed Care Interface* 1998;11(1).

MIMI VEGA 01559

Reynolds M. Delgado III, MD, FACC  
Page 9  
10/19/2009

4. **Delgado III RM**, Radovancevic B, Springer A, Gould L, Frazier OH. Improvement of reversible ischemia in severe post transplant coronary artery disease. *Tex Heart Inst J* 1998;25(2):145-9.
5. **Delgado III RM**, Radovancevic B, Massin EK, Frazier OH, Benedict C. Neurohormonal changes following implantation of the left ventricular assist device and implications for its weanability. *ASAIO* 1998;444:299-300.
6. Beyer E, Vatcharasiritham C, Sweeney M, Przybylowski P, **Delgado III RM**, Radovancevic B, Frazier OH. Linked pacing after heterotopic heart transplantation with concurrent left ventricular reduction of the native heart. *Tex Heart Inst J* 1998;25:299-302.
7. **Delgado III RM**, Massin EK, Cooper J. Acute heart failure. *Tex Heart Inst J* 1998;25:255-59.
8. Willerson JT, **Delgado III RM**, Mann D. Treating relentlessly progressive congestive heart failure: what next? *Tex Heart Inst J* 1998;25(4):235-37.
9. Willerson JT, **Delgado III RM**, Mann D. Relentlessly progressive congestive heart failure: new therapies for the future. *Quar J of Card* 1999;4(1):1A-3A.
10. **Delgado III RM**, Willerson JT. Pathophysiology of heart failure: a look at the future. *Tex Heart Inst J* 1999;26(1):28-33.
11. Torre-Amione G, Stetson SJ, Youker KA, Durand JB, Radovancevic B, **Delgado III RM**, Frazier OH, Entman ML, Noon GP. Decreased expression of tumor necrosis factor- $\alpha$  in failing human myocardium after mechanical circulatory support. *Circulation* 1999;100(11):1189-93.
12. Radovancevic B, Konuralp C, Radovancevic R, Vaughn W, Thomas C, Zaqqi M, **Delgado III RM**, Frazier OH. Factors predicting survival beyond 10 years following heart transplantation. *J Heart Lung Transplant* 2000;19(1):78.
13. Beyer EA, McMullan DM, **Delgado III RM**, Gregoric ID, Radovancevic B, Frazier OH. Normalization of native heart function several years after heterotrophic heart transplantation: a case report. *Ann Thorac Surg* 2000;70(5):1690-2.
14. **Delgado III RM**. Review of Cardiac Assist Devices. *Tex Heart Inst J* 2000 June;27(2):225-26.
15. **Delgado III RM**, Razeghi P, Radovancevic B. Effective treatment of severe acute myocarditis with intravenous immune globulin and pulse corticosteroids in a 32-year-old patient. *Congest Heart Fail* Sept-Oct 2000;6(5):277-9.

MIMI VEGA 01560

Reynolds M. Delgado III, MD, FACC  
Page 10  
10/19/2009

16. **Delgado III RM**, Eastwood C, Jax T. Successful weaning from milrinone of a patient with severe congestive heart failure using Carvedilol. *Congest Heart Fail* Jan-Feb 2001;7(1):47-50.
17. Khan T, Okerberg K, Hernandez A, Miller K, Myers T, Radovancevic B, **Delgado III RM**, Gregoric ID, Frazier OH. Assessment of myocardial recovery using dobutamine stress echocardiography in LVAD patients. *J Heart Lung Trans* Feb 2001;20(2):202-203.
18. Frazier OH, Gregoric ID, **Delgado III RM**, Myers T, Radovancevic B, Khan T, Miller K, Ho J, Jarvik R. Initial experience with the Jarvik 2000 Left Ventricular Assist System as a bridge to transplantation: report of 4 cases. *J Heart Lung Trans* Feb 2001;20(2):201.
19. **Delgado III RM**, Zewail A. Intravenous milrinone in treatment of advanced congestive heart failure. *Tex Heart Inst J*, 2003; 30:109-13
20. Frazier OH, Myers TJ, Gregoric ID, Khan T, **Delgado III RM**, Croitoru M, Miller K, Westaby S, Jarvik R. Initial clinical experience with the Jarvik 2000 Implantable Axial-Flow Left Ventricular Assist System. *Circulation* June 18, 2002;105(24):2855-2860.
21. **Delgado III RM**. Heart transplantation: a review. *Circulation*, Oct. 2002; 106:128e
22. Khan T, **Delgado III RM**, Radovancevic B, Torre-Amione G, Abrams J, Miller K, Myers T, Frazier OH. Dobutamine stress echocardiography predicts myocardial improvement in patients supported by left ventricular assist devices (LVADS): hemodynamic and histologic evidence of improvement before LVAD explantation. *J Heart Lung Trans* 2003 Feb;22(2):137-46.
23. Vrtovec B, **Delgado III RM**, Zewail A, Thomas CD, Richartz BM, Radovancevic B. Prolonged QTc interval and high B-type natriuretic peptide levels together predict mortality in patients with advanced heart failure. *Circulation* 2003 Apr 8;107(13):1764-9. Epub 2003 Mar 24.
24. **Delgado III RM**. The future of mechanical circulatory support. *Curr Opin Cardiol*. 2003 May;18(3):199-209. Review.
25. Zewail AM, Nawar M, Vrtovec B, Eastwood C, Kar MN, **Delgado III RM**. Intravenous milrinone in treatment of advanced congestive heart failure. *Tex Heart Inst J* 2003;30(2):109-13.
26. Letsou GV, Myers TJ, Gregoric ID, **Delgado III RM**, Shah N, Robertson K, Radovancevic B, Frazier OH. Continuous axial-flow left ventricular assist device (Jarvik 2000) maintains kidney and liver perfusion for up to 6 months. *Ann Thorac Surg* 2003 Oct;76(4):1167-70.

MIMI VEGA 01561

Reynolds M. Delgado III, MD, FACC  
Page 11  
10/19/2009

27. Letsou GV, Carter JE, Shenag S, Gregoric ID, **Delgado III RM**, Frazier OH. Orthotopic cardiac transplantation 30 months after successful dynamic cardiomyoplasty. *Ann Thorac Surg* 2003 Oct;76(4):1289-91.
28. Frazier OH, **Delgado III RM**. Mechanical circulatory support for advanced heart failure: where does it stand in 2003? *Circulation* 2003 Dec 23;108(25):3064-8.
29. Frazier OH, **Delgado III RM**, Scroggins N, Odegaard P, Kar B, Radovancevic B, Broom C. Mechanical bridging to improvement in severe acute 'nonischemic, nonmyocarditis' heart failure. *Congestive Heart Failure* Mar-Apr 2004;10(2):109-113.
30. **Reynolds III RM**, Nawar MA, Zewail AM, Kar B, Vaughn WK, Wu KK, Aleksic N, Sivasubramanian N, McKay K, Mann DL, Willerson JT. COX-2 inhibitor treatment improves left ventricular function and mortality in a murine model of doxorubicin-induced heart failure. *Circulation*, 2004 Mar 23;109(11):1428-33
31. Kar B, Butkevich A, Civitello AB, Nawar MA, Walton B, Messner GN, Gregoric ID, Feldman J, Myers TJ, Gemmato C, **Delgado III RM**. Hemodynamic support with a percutaneous left ventricular assist device during stenting of an unprotected left main coronary artery. *Tex Heart Inst J*, 2004; 31(1):84-86
32. Frazier OH, Shah NA, Myers TJ, Robertson KD, Gregoric, **Delgado RM III**. Use of the flowmaker (Jarvik 2000) left ventricular assist device for destination therapy and bridging to transplantation. *Cardiology* 2004;101:111-116.
33. **Delgado RM III**. Mechanical support emerging for treatment of heart failure. *Houston Medicine* 2004;2(1):68-70.
34. Frazier OH, **Delgado RM III**, Kar B, Patel V, Gregoric ID, Myers TJ. First clinical use of the redesigned HeartMateII left ventricular assist device in the United States: a case report. *Tex Heart Inst J* 2004;31(2):157-159. THI
35. Wadia Y, **Delgado III RM**, Odegaard P, Frazier OH. Jarvik 2000 FlowMaker axial-flow left ventricular assist device support for management of refractory ventricular arrhythmias. *Congest Heart Fail* 2004 Jul-Aug;10(4):195-6.
36. Kar B, **Delgado III RM**, Wadia Y. Treating cardiogenic shock using a percutaneous ventricular assist device-a case series. *Business Briefing: US Cardiology* 2004 Aug; 97-98.
37. Miller K, Myers TJ, Robertson K, Shah N, **Delgado III RM**, Gregoric ID. Quality of life in bridge-to-transplant patients with chronic heart failure after implantation of an axial-flow ventricular assist device. *Congest Heart Fail* 2004 Sep-Oct;10(5):226-9.
38. Letsou GV, Shah N, Gregoric ID, Myers TJ, **Delgado RM III**, Frazier OH. Gastrointestinal bleeding from arteriovenous malformations in patients supported by the

Reynolds M. Delgado III, MD, FACC  
Page 12  
10/19/2009

MIMI VEGA 01562



Jarvik 2000 axial flow left ventricular assist device. *J Heart Lung Transplant*. 2005 Jan;24(1):105-9.

39. Amir O, Kar B, **Delgado RM III**, Younis AG, Gregoric ID, Smart FW, Radovancevic B, Frazier OH. Images in cardiovascular medicine. High left ventricular assist device flows resulting from combined native aortic valve and outflow valve regurgitation. *Circulation* 2005 Feb 1;111(4):e34.

40. **Delgado RM III**, Frazier OH, Myers TJ, Gregoric ID, Robertson K, Shah NA, Kar B. Direct thrombolytic therapy for intraventricular thrombosis in patients with the Jarvik 2000 left ventricular assist device. *J Heart Lung Trans* 2005 Feb; 24 (2): 231-3.

41. Blaitnead M, Wadia Y, Messner G, Allison P, Harati Y, **Delgado RM III**. West Nile virus infection after cardiac transplantation. *Jour of Heart and Lung Trans*. 2005;24:774-6.

42. Albrecht CA, Giesler GM, Kar B, Hariharan R, **Delgado RM III**. Intravenous milrinone infusion improves congestive heart failure caused by diastolic dysfunction. *Tex Heart Inst J* 2005; 32:220-3.

43. Long J, Kfoury AG, Slaughter, Silver M, Milano C, Rogers J, **Delgado RM III**. Long-term destination therapy with the HeartMate XVE left ventricular assist device: Improved outcomes since the REMATCH study. *Cong Heart Failure* 2005 May-June 133-8.

44. **Delgado RM III**, Palanichamy N, Radovancevic R, Vrtotec B, Radovancevic B. Brain Natriuretic Peptide Levels and Response to Cardiac Resynchronization Therapy in Heart Failure Patients. *Congest Heart Fail* Sept-Oct 2006;12(5)250-3.

45. **Delgado RM III**, Nawar M, Loghin C, Myers TJ, Gregoric ID, Pool T, Scroggins N, Radovancevic B, Frazier OH. Catheterization of the AbioCor™ Implantable Replacement Heart: Evaluation of the Unique Physiology Created by the Device. *Tex Heart Inst J* 2006;33:359-360.

#### Textbook Chapters

1. **Reynolds Delgado III**, Heinrich Tagetmeyer "Heart Failure and Resuscitation", chapter 37, Modern Surgical Care: Physiologic Foundations and Clinical Applications, ed. Thomas A. Miller, Quality Medical Publishing, 1998.
2. O.H. Frazier, Stephen Westaby, **Reynolds Delgado III**, "Mechanical Circulatory Support: Present Options and Long Term Support", Ischemic Heart Disease: Surgical Management, eds. Buxon, Westaby and Frazier, Mosby International Ltd, London, England, Nov 1998.

MIMI VEGA 01563

Reynolds M. Delgado III, MD, FACC  
Page 13  
10/19/2009



3. O.H. Frazier, **Reynolds Delgado III**, "Use of Mechanical Devices in Treating Heart Failure", chapter 30, Congestive Heart Failure: Pathophysiology, Differential Diagnosis and Comprehensive Approach to Therapy, second edition, eds. Hosenpud and Greenberg, Lippincott, Williams & Wilkins, Baltimore, MD, 2000, pp. 571-582.
4. **Reynolds Delgado III**, O.H. Frazier, Heinrich Tagetmeyer, "Mechanical Circulatory Support in Patients with Heart Failure", chapter 43, Heart Failure: A Companion to Braunwald's Heart Disease, ed. Douglas Mann, W.B. Saunders Company, 2003
5. **Reynolds Delgado III**, James T. Willerson, "Congestive Heart Failure: Contemporary Medical Therapy", chapter 31, Section IV: Pathogenetic basis of management of cardiomyopathies, Heart Failure/Pathogenesis and Treatment, eds. Jagat Narula, Renu Virmani, Manel Ballester, Ignasi Carrio, Stephen Westaby, O.H. Frazier, and James T. Willerson, Martin Dunitz Ltd. a member of the Taylor & Francis group, London, UK, 2002, pp. 557-567.
6. **Reynolds Delgado III**, James T. Willerson, Douglas Mann, "Relentlessly Progressive Congestive Heart Failure: Can It Be Prevented?", chapter 37, Section V: Pathogenetic basis of surgical management in end-stage heart failure, Heart Failure/Pathogenesis and Treatment, eds. Jagat Narula, Renu Virmani, Manel Ballester, Ignasi Carrio, Stephen Westaby, O.H. Frazier, and James T. Willerson, Martin Dunitz Ltd. a member of the Taylor & Francis group, London, UK, 2002, pp.695-698.
7. **Reynolds Delgado III**, EDITOR, Harvinder Arora, Associate Editor. Interventional Treatment of Advanced Ischemic Heart Disease. Springer-Verlag-London LTD, 2009.
8. **Reynolds Delgado III**, "Mechanical Circulatory Support in Patients with Heart Failure", Heart Failure: A Companion to Braunwald's Heart Disease, ed. Douglas Mann, W.B. Saunders Company, 2010.

Other Publications

1. "Case Studies in Advanced Heart Failure Management" CD Rom, Sanofi-Synthelabo, Inc., January 2000.
2. Patient Education Material on Transplantation, Sanofi-Synthelabo, Inc. educational grant, 2000.
3. Lane R. Miller, Tehreen Khan, **Reynolds Delgado**, Raymond F. Steinback "Congenital Absence of the Pericardium", posted to Texas Heart Institute Cardiac Society Website.
4. **Reynolds Delgado** "Total Artificial Heart Case Studies", posted to Heart Surgery Forum Website.

Reynolds M. Delgado III, MD, FACC  
Page 14  
10/19/2009

MIMI VEGA 01564

## ***RESEARCH PROJECTS***

### ***Clinical Studies***

Principal Investigator, Neurohormonal changes following implantation of LVAD (HeartMate), Approved: June 1995. Status: Complete.

Investigator, Predictors of outcome in patients awaiting cardiac transplantation. Approved: June 1996. Status: Complete.

Investigator, A phase 3, open label titration study of the chronic efficacy and safety of OPC 18790 for the treatment of patients with heart failure (103-95-202). Approved: 1997. Status: Complete.

Investigator, Multicenter, randomized study of the long-term hemodynamic effects and safety of the dual metalloprotease inhibitor (DMP-i) BMS-186716 in the treatment of heart failure (CV137-012). Approved: 1997. Status: Complete

Investigator, Evaluation of the safety/tolerability of long-term treatment with the DMP Inhibitor BMS-186716 or Lisinopril in Subjects with Heart Failure (CV137-018). Approved: 1997. Status: Complete.

Investigator, Myocardial repair by mechanical unloading: Cytokines growth factors and receptors, and the neurohormonal and adrenergic renin-angiotensin system. Approved: 1997. Status: Complete.

Investigator, Interleukin 6 as a predictor of response to therapy for acute rejection after cardiac transplantation. Approved: 1997. Status: Complete.

Investigator, Losartan in Heart Failure Trial, ELITE 1. Approved: 1997. Status: Complete.

Investigator, A Phase 3 open label titration study of the chronic efficacy and safety of OPC-18790 for the treatment of patients in heart failure. Approved: Pending. Status: Complete.

Investigator, Randomized evaluation of mechanical assistance for treatment of congestive heart failure. The REMATCH Trial. Status: Complete.

Investigator, Use of Nitric Oxide to Treat Acute Right Ventricular Failure and Pulmonary Hypertension. Approved: 1999. Status: Complete.

Investigator, SCO-HEFT trial, Evaluation of AICD versus Amiodarone versus Neither in Congestive Heart Failure. Approved: 1999. Status: Complete.

MIMI VEGA 01565

Reynolds M. Delgado III, MD, FACC  
Page 15  
10/19/2009

Principal Investigator, SB214242 trial, Use of Endothelin Antagonist in the Treatment of Heart Failure. Approved: 1999. Status: Complete.

Investigator, Clinical trial of transmyocardial revascularization (TMR) using the Heart Laser CO2 laser system for the treatment of transplant coronary artery disease (CAD). Approved: 1999. Status: Complete.

Investigator, A double-blind, placebo-controlled randomized study to assess the efficacy and safety of Zenapax in combination with Mycophenylate Mofetil, cyclosporin and corticosteroids in patients undergoing cardiac transplantation. Status: Complete.

Principal Investigator, A double-blind, parallel-group, multi-center, randomized, placebo-controlled study to assess the efficacy (symptomatology) and safety of Ro 61-0612 (tezosentan) in patients with acute decompensated heart failure. Status: Complete.

Principal Investigator, A double-blind, parallel-group, multi-center, randomized, placebo-controlled study to assess the efficacy (hemodynamics and symptoms) and safety of Ro 61-0612 (tezosentan) in patients with acute decompensated heart failure. Status: Complete.

Principal Investigator, Prospective evaluation and identification of decompensation in patients with heart failure by impedance cardiography test. Status: Active.

Principal Investigator, Enhanced external counterpulsation (EECP) in heart failure: a single blind, controlled, randomized evaluation of the efficacy and safety. Status: Active.

Investigator, A pilot, two center, comparative trial of tacrolimus and steroids in combination with rapamune or CellCept following primary heart transplantation. Status: Active.

Investigator, First Clinical Protocol for Evaluation of the Jarvik 2000 Heart Assist System. Approved: 2000. Status: Active.

Principal Investigator, Home I.V. Milrinone quality of life study in patients with Class IV heart failure. Approved: 2000. Status: Complete.

Investigator, A phase II, double-blind, randomized, placebo-controlled dose comparative study of the efficacy, tolerability and safety of MCC-135 in subjects with chronic heart failure, NYHA II/III. Approved: 2001. Status: Active.

Investigator, Retrospective and prospective chart review of medical treatment for elevated panel relative antibodies in transplant candidates. Approved: 2001. Status: Active.

Investigator, Multi-site pacemaker and AICD therapy in severe heart failure, COMPANION Trial. Approved: 2001. Status: Completed.

MIMI VEGA 01566

Reynolds M. Delgado III, MD, FACC  
Page 16  
10/19/2009

Investigator, AbioCor total artificial heart for human use. Approved: 2001. Status: Active.

Investigator, Cardioad mechanical auxiliary ventricles. Approved: 2001. Status: Active.

Principal Investigator- Acute Decompensated Heart Failure Registry (AHDERE). Sponsor: Scios 2001, Status: Active.

Principal Investigator- Management of Patients with CHF after Hospitalization – Follow-Up Serial Infusion of Natrecor – Fusion 1, A Pilot Study. Sponsor: Scios, 2002 Status: Closed

Physician Champion- OPTIMIZE-HF -Organized Program To Initiate life-saving treatment in hospitalized patients with Heart Failure. Sponsor: GlaxoSmithKline 2003 Status: Active

Principal Investigator- Non-Randomized Assessment of Natrecor (Nesiritide) for Reversal of Pulmonary Hypertension in Patients with Severe Heart Failure. Sponsor: Scios, Status: Active

Principal Investigator- Noninvasive Detection of Cardiac Allograft Rejection Using Serial B-Type Natriuretic Peptide Monitoring. Sponsor: Roderick MacDonald Research Fund (\$20,000) 2002, Status: Closed

Principal Investigator- The Utility of High Resolution ECG in Cardiac Transplant Recipients with Allograft Coronary Artery Disease. 2001, Status: Active

Principal Investigator- The Utility of High Frequency QRS ECG in the Diagnosis and Management of Cardiomyopathy. Sponsor: Roderick MacDonald Research Fund (\$21,781) 2003, Status: Closed

Principal Investigator- VERITAS-1-Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study to Assess the Efficacy, Safety and Tolerability of Tezosentan in Patients with Acute Heart Failure. Sponsor: ACTELION, Status: Closed

Principal Investigator- Retrospective Chart Review: Effect of Administration of Recombinant Human Erythropoietin in Heart Failure Patients. 2003, Status: Active

Principal Investigator- Registry of Cardiac Resynchronization Therapy (RESTORE-US). Sponsor: Access Medical Group, Ltd. 2003, Status: Closed

Co-investigator- CHRONICLE® Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure (COMPASS-HF). Sponsor: Medtronic 2003, Status: Active

MIMI VEGA 01567

Reynolds M. Delgado III, MD, FACC  
Page 17  
10/19/2009



Principal Investigator-A Multi-Centered, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study to Assess the Effects of VASOGEN'S Immune Modulation Therapy (CELACADE™) on Mortality and Morbidity in Patients with Chronic Heart Failure-ACCLAIM. Sponsor:VASOGEN, Inc. 2004, Status: Active

Co-Investigator-A Prospective Evaluation of Closed-Loop Stimulation in Heart Failure Patients (HF-CLS). Sponsor:BIOTRONIK 2004, Status: Active

Principal Investigator-A Phase-2, Dose Escalation Evaluation of the Pharmacokinetic and Hemodynamic Effects of CARPERTIDE in Subjects with Congestive Heart Failure. Sponsor-Fujisawa Healthcare, Inc., 2004, Status: Active

Co-Investigator-A Six-Month, Multicentered, Randomized, Open Label Study of the Safety, Tolerability and Efficacy of Two Neoral® Doses in Addition to Certican™ and Steroids in *de novo* Heart Transplant Recipients. Sponsor-Novartis 2004, Status-Active

Principal Investigator-Mechanisms of Particulate Matter Associated Exacerbation of Endothelial Dysfunction. Sponsor-Roderick MacDonald Research Fund (\$50,000), Status-Active

Co-Investigator-Comparison of Two Methods of Measuring Central Venous Pressures. Sponsor-Roderick MacDonald Research Fund (\$4,774) 2004, Status-Active

#### Basic Science Studies

Development of an Animal Model of Heart Failure and Study of Immunomodulating Agents in Preventing the Progression of Heart Failure.

Development of a novel method if in vivo mouse echocardiography using an intravascular ultrasound catheter.

Study of a Matrix Metalloproteinase Inhibitor on Left Ventricular Remodeling and Function in a Mouse Model of Heart Failure. Status: Active.

Study of a Cyclooxygenase Type II Inhibitor on Left Ventricular Remodeling and Function in a Transgenic Mouse Model of Heart Failure. Status: Active.

#### **PRESENTATIONS & MEETINGS**

1. "Improved Left Ventricular Function After Chronic Left Ventricular Unloading", 32<sup>nd</sup> Annual Meeting of the Society of Thoracic Surgeons, January 29-31, 1996, Orlando, Florida.

MIMI VEGA 01568

Reynolds M. Delgado III, MD, FACC  
Page 18  
10/19/2009



2. "Neurohormonal Changes Following Implantation of the Left Ventricular Assist Device and Implications for Its Weanability", 17<sup>th</sup> Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation, April 2-5, 1997, London, England.
3. Ten Years of Cardiac Transplantation in The National Medical Center La Raza sponsored by Insituto Mexicano del Seguro Social, Mexico City, Mexico, May 29, 1998.
4. Co-Moderator and presenter, First Symposium on Congestive Heart Failure sponsored by the Texas Heart Institute, Houston, Texas, November 5-6, 1998.
5. "Safety and Diagnostic Accuracy of Adenosine 99M-TC Tetrafosmin SPECT Imaging with a 4 Minute Infusion Protocol", 4<sup>th</sup> International Conference of Nuclear Cardiology, April 18-21, 1999, Athens, Greece.
6. "In vivo Murine Cardiac Transthoracic Imaging Using a High Frequency Intravascular Ultrasound Probe", American Heart Association's Scientific Conference on Molecular, Cellular and Integrated Physiological Approaches to the Failing Heart, August 18-22, 1999, Salt Lake City, Utah.
7. "Clinical Experience with Continuous Home Milrinone Combined with Beta Blocker Therapy in Severe Congestive Heart Failure", 3<sup>rd</sup> Annual Meeting of the Heart Failure Society of America, Inc., September 22-25, 1999, San Francisco, California.
8. "Improvement in Left Ventricular Systolic Function with a Cyclooxygenase-II Inhibitor in a Murine Adriamycin Heart Failure Model", American Heart Association's 72<sup>nd</sup> Scientific Sessions, November 7-10, 1999, Atlanta, Georgia.
9. "Medical Treatment of Heart Failure: The Fundamentals", Second Symposium on Congestive Heart Failure, Texas Heart Institute, Houston, Texas, May 4-5, 2000.
10. Heart Failure Thought Leader Forum, Paris, France, April 27-30, 2000.
11. "Implementation and outcomes of a hospital-based heart failure program to support private practice cardiologists", Heart Failure Society of America Conference, Boca Raton, Florida, September, 2000.
12. "LVAS Explanation: Hemodynamic Assessment with Dobutamine Stress Test Studies" American Heart Association Congestive Heart Failure Conference, New Orleans, Louisiana, October, 2000.
13. Management of Refractory Chronic Heart Failure in the Outpatient Setting: roundtable meeting, Puerto Rico, October 19-22, 2000.

MIMI VEGA 01569

Reynolds M. Delgado III, MD, FACC  
Page 19  
10/19/2009

14. Speaker, Carvedilol Consultants' Educational Update Forum East, Boca Raton, Florida, March 30-April 1, 2001.
15. "Role of Cyclooxygenase 1 and 2 in Health and Disease" for Merck, Houston, Texas, April 3, 2001.
16. "Mechanical Devices and Cardiac Transplantation", TIRR, Houston, Texas, April 20, 2001.
17. "New Therapies in the Treatment of Congestive Heart Failure" at the Annual Meeting of the Texas Academy of Family Physicians, Houston, Texas, May 3, 2001.
18. "The Use of Beta Blockers in the Treatment of Congestive Heart Failure" at the Annual Meeting of the Texas Academy of Family Physicians, Houston, Texas, May 7, 2001.
19. Success with Heart Failure: New Strategies to Reverse Acute Decompensation, Denver, Colorado, July 14, 2001.
20. "First Clinical Use of the Jarvik 2000 as a Bridge to Transplantation: Hemodynamic Effects", 47<sup>th</sup> Annual American Society of Artificial Organs Conference, New York, New York, June 7-10, 2001.
21. Heart Failure Clinical Database Investigators Meeting, San Diego, California, June 22-24, 2001.
22. "Use of the Jarvik 2000 Left Ventricular Assist System as a Bridge to Transplantation: A Report of the First 10 Cases", Heart Failure Society of America 5<sup>th</sup> Scientific Meeting, Washington, D.C., September 9-12, 2001.
23. "THI Experience of Myocardial Recovery and Weaning", International Society for Heart and Lung Transplantation 3<sup>rd</sup> Fall Education Meeting, Mechanical Cardiac Support and Replacement II, Anaheim, California, November 9-10, 2001.
24. "Effects of Prolonged Partial Pulsatile Flow in Patients Treated with the Jarvik 2000 Ventricular Assist Device", American Heart Association 74<sup>th</sup> Annual Scientific Sessions, Anaheim, California, November 12, 2001.
25. "The Role of Inotropic Agents in the Management of Acute Heart Failure", Medical Management of Acute Heart Failure in the New Millennium Conference, Houston, Texas, December 8, 2001.
26. Moderator "Pacemakers and Defibrillators for the New Era", Third Symposium on Cardiac Arrhythmias: New Pharmacologic and Interventional Strategies, Houston, Texas, February 16, 2002.

MIMI VEGA 01570

Reynolds M. Delgado III, MD, FACC  
Page 20  
10/19/2009

27. ADHERE Investigator National Heart Failure Registry Meeting, Atlanta, GA, March 1-3, 2002.
28. Invited Speaker, AbioCor Clinical Grand Rounds, Washington, D.C., May 5, 2002.
29. "The Unique Physiology of the AbioCor Total Artificial Heart in the Patient with Severe Congestive Heart Failure", 48<sup>th</sup> Annual American Society of Artificial Organs Conference, New York, New York, June 13-15, 2002.
30. "Quality of Life Assessment in Patients Supported with the Jarvik 2000 Heart Assist Device and Bridged to Transplant", 48<sup>th</sup> Annual American Society of Artificial Organs Conference, New York, New York, June 13-15, 2002.
31. Heart Failure Mountaintop Retreat, Lakewood, Colorado, August 15-18, 2002.
32. "The Unique Physiology of the AbioCor Total Artificial Heart in the Patient with Severe Congestive Heart Failure", Heart Failure and Circulatory Support Summit, Cleveland, Ohio, August 22-25, 2002.
33. "Serum Levels of B-Type Natriuretic Peptide After Cardiectomy and Implantation of a Total Artificial Heart", 6<sup>th</sup> Annual Heart Failure Society of America Scientific Meeting, Boca Raton, Florida, September 22-25, 2002.
34. "Relationship Between Plasma B-Type Natriuretic Peptide Levels and Renal Function", 6<sup>th</sup> Annual Heart Failure Society of America Scientific Meeting, Boca Raton, Florida, September 22-25, 2002.
35. "IV Milrinone and Beta Blocker Combination Therapy in Outpatients with Severe Congestive Heart Failure", 6<sup>th</sup> Annual Heart Failure Society of America Scientific Meeting, Boca Raton, Florida, September 22-25, 2002.
36. "Review of Heart Failure Guidelines", 3<sup>rd</sup> Symposium on Congestive Heart Failure: A Comprehensive Update on Medical and Surgical Management, Texas Heart Institute, Houston, Texas, October 3-4, 2002.
37. Session Moderator- 3<sup>rd</sup> Symposium on Congestive Heart Failure: A Comprehensive Update on Medical and Surgical Management, Texas Heart Institute, Houston, Texas, October 3-4, 2002.
38. ACCLAIM Study Expert Panel Meeting, Chicago, Illinois, October 18, 2002.
39. "Contemporary Concepts in Congestive Heart Failure" Concepts in Contemporary Cardiology Conference, Houston, Texas, October 23-26, 2002.
40. New Options in Heart Failure Management: Integration of Device Therapy, Washington, D.C., November 1-2, 2002.

*Reynolds M. Delgado III, MD, FACC*

Page 21

MIMI VEGA 01571

10/19/2009

41. American Heart Association 75<sup>th</sup> Annual Scientific Sessions, Chicago, Illinois, November 17-20, 2002.
42. Chairman- Managing High-Risk Patients: Integration of Device Therapies Conference, Vail, Colorado, January 10-11, 2003.
43. Steering Committee Meeting, ADVANCENT Heart Failure Registry, Chicago, Illinois, January 22, 2003.
44. Course Director- New Advances and Novel Treatments for Congestive Heart Failure, Houston, Texas, February 20, 2003.
45. "Vascular Thrombosis in Patients with Long-Term Jarvik 2000 VAD Support" International Society for Heart and Lung Transplantation 23<sup>rd</sup> Annual Meeting and Scientific Sessions, Vienna, Austria, April 9-12, 2003.
46. Heart Failure and Anemia Regional Advisory Board Meeting, San Francisco, California, September 5-7, 2003.
47. "Use of Systolic Time Ratio and B-Type Natriuretic Peptide to Predict Mortality in Patients with Heart Failure" Heart Failure Society of America 7<sup>th</sup> Annual Scientific Meeting, Las Vegas, Nevada, September 21-24, 2003.
48. "Rationale and Methodology of a National Registry for Heart Failure Patients with Left Ventricular Dysfunction: The ADVANCENT Project" Heart Failure Society of America 7<sup>th</sup> Annual Scientific Meeting, Las Vegas, Nevada, September 21-24, 2003.
49. "Perioperative Use of Nesiritide in Heart Failure Patients Undergoing Implantation of a Left Ventricular Assist Device" Heart Failure Society of America 7<sup>th</sup> Annual Scientific Meeting, Las Vegas, Nevada, September 21-24, 2003.
50. "LVAD's as Destination Therapy", Adhere LM Investigator Meeting, Houston, Texas, October 10-12, 2003.
51. Chairman- New Modalities for Treating Heart Failure Symposium, Brownsville, Texas, October 24-25, 2003.
52. Program Moderator- Congestive Heart Failure Summit, Texas Heart Institute, Houston, Texas, November 6, 2003.
53. "Evaluation of Reversibility of Pulmonary Hypertension in Heart Transplant Candidates", American Heart Association Scientific Session, Orlando, Florida, November 9-12, 2003.

MIMI VEGA 01572

Reynolds M. Delgado III, MD, FACC  
Page 22  
10/19/2009



54. Invited Speaker- "Total Artificial Heart Case Studies", Cardiothoracic Surgery Experts Forum, Webconference, November 24, 2003.
55. "Implantable Long-term Support Devices", First International Conference on Heart Failure in Children and Young Adults: From Molecular Mechanisms to Medical and Surgical Strategies", Houston, Texas, December 3-6, 2003.
56. Co-Chairman- "Mechanical Support of the Failing Heart for the Cardiologist", Texas Heart Institute Satellite Symposium to the American College of Cardiology Scientific Session, New Orleans, Louisiana, March 6, 2004.
57. Featured Poster- "Effect of Nesiritide on Renal Function After Implantation of the AbioCor Total Artificial Heart", 53<sup>rd</sup> Annual American College of Cardiology Scientific Session, New Orleans, Louisiana, March 7-10, 2004.
58. "The Utility of High Frequency QRS ECG in the Diagnosis of Cardiomyopathy", 53<sup>rd</sup> Annual American College of Cardiology Scientific Session, New Orleans, Louisiana, March 7-10, 2004.
59. Invited Faculty Speaker- 2<sup>nd</sup> Annual Symposium on Heart Failure and Cardiomyopathy, Kansas City, Kansas, April 3, 2004.
60. "Use of Nesiritide in the CT Surgical Patients with Heart Failure", Dallas, Texas, April 17, 2004
61. Co-Chairman- "Applications and Perspectives: Perioperative Management of the Cardiac Surgery Patient", a CME-accredited symposium presented at the 84<sup>th</sup> Annual American Association for Thoracic Surgeons Symposium, Toronto, Canada, April 27, 2004
62. "Evolving Indications for Chronic LVAD Support", The Implantable Left Ventricular Assist Device: from Concept to Clinical Reality, Texas Heart Institute, Houston, Texas, May 21-22, 2004.
63. Invited Speaker- "Practical Applications" as part of "Anemia in Heart Failure: Understanding the Clinical and Therapeutic Implications" Satellite Symposium presented at the 8<sup>th</sup> Annual Scientific Meeting, Heart Failure Society of America, Toronto, Canada, September 12, 2004.
64. Invited Speaker- "Lessons from ADVACENT about Outpatient Management of Chronic Heart Failure in US" as part of "What National/International Heart Failure Registries Teach Us about Heart Failure" Satellite Symposium presented at the 8<sup>th</sup> Annual Scientific Meeting, Heart Failure Society of America, Toronto, Canada, September 13, 2004.

MIMI VEGA 01573

*Reynolds M. Delgado III, MD, FACC*  
Page 23  
10/19/2009

65. Chairman, Thoratec Satellite Symposium- "Mechanical Circulatory Support for the Treatment of Heart Failure: Current and Emerging Trends" presented at the 8<sup>th</sup> Annual Scientific Meeting, Heart Failure Society of America, Toronto, Canada September 12, 2004.
66. Poster presentation- "Confusion at Large: Incorrect Assignment of Patients to the AHA/ACC Stages of Heart Failure in the ADVANCENT Registry", 8<sup>th</sup> Annual Scientific Meeting, Heart Failure Society of America, Toronto, Canada, September 13, 2004.
67. Poster presentation- "Recombinant Human Erythropoietin in Anemic Heart Failure Patients, 8<sup>th</sup> Annual Scientific Meeting, Heart Failure Society of America, Toronto, Canada, September 13, 2004.
68. Moderated poster- "Effects of Nesiritide on Pulmonary Hypertension in Heart Transplant Candidates", 8<sup>th</sup> Annual Scientific Meeting, Heart Failure Society of America, Toronto, Canada, September 12, 2004.
69. Invited Speaker- "Soporte Mecanico en el Manejo de la Insuficiencia Cardica Comida" presented at the XXV Curso Intraamericano Sobre Hipertension Arterial, Aterosclerosis, Cardiopatia Isquemica E Insuficiencia Cardiaca, Acapulco, Guerrero October 8-10, 2004.
70. Program Moderator- Session IV-Texas Heart Institute, 4<sup>th</sup> Symposium on Congestive Heart Failure, co-sponsored by American Heart Association, Texas Affiliate, Houston, Texas, October 21-22, 2004.
71. Invited Speaker-Texas Heart Institute, 4<sup>th</sup> Symposium on Congestive Heart Failure, "Management of Chronic Heart Failure: The Guidelines and Beyond", October 21-22, 2004.
72. Faculty Member-Heart Failure Summit 2004, "Novel Therapies for Heart Failure", Texas Heart Institute, Houston, Texas, November 4, 2004.
73. Co-Chairman-"Mechanical Support of the Failing Heart", Texas Heart Institute Satellite Symposium prior to American Heart Association Annual Meeting, New Orleans, Louisiana, November 6, 2004.
74. Poster presentation-"Endothelial Function in Patients with Pulsatile or Axial-Flow Ventricular Assist Device (LVAD) Support", American Heart Association Annual Meeting, New Orleans, Louisiana, November 6, 2004.
75. Invited Speaker-Society of Thoracic Surgeons 41<sup>st</sup> Annual Meeting, "Neurohormonal Approach in Patients with Ventricular Dysfunction: Rationale and Principles" January 22-26, 2005, Tampa, Florida

MIMI VEGA 01574

Reynolds M. Delgado III, MD, FACC  
Page 24  
10/19/2009

76. Invited Speaker-AHA-Annual Cardiology Update Conference-"ESAD: Biventricular Pacing in Cardiac Therapy", El Paso, Texas February 11, 2005
77. Poster presentation-"Body Temperature <97° is Associated with Increased B-Type Natriuretic Peptide and Worse Response to Therapy in Heart Failure Patients", ISHLT-April 6-9, 2005, Philadelphia, Pennsylvania.
78. Poster presentation-"Digoxin Therapy Increases Mortality Only in Female Heart Patients with a Prolonged QTc Interval, ISHLT-April 6-9, 2005, Philadelphia, Pennsylvania.
79. Invited speaker-Concepts in Contemporary Cardiology Conference-"Management of Acute and Chronic Heart Failure with Left Ventricular Assist Devices" April 2005, Houston, Texas
80. Invited speaker-South Texas Symposium on Cardiovascular Health: Advances in the Treatment of Cardiovascular Disease, - April 22-23, 2005, South Padre Island, Texas
81. Slide presentation-"Use of the TandemHeart Percutaneous Left Ventricular Assist Device for Support of the Failing Heart, The Texas Heart Institute Experience" ASAIO-June 9-11, 2005, Washington DC
82. Slide presentation-"Long-term Destination Therapy with the HeartMateXVE Left Ventricular Assist Device: Improved Outcomes Since the REMATCH Study" ASAIO-June 9-11, 2005, Washington DC
83. Poster presentation-"Is Supplemental Thyroxine Therapy Indicated in Advanced Heart Failure Patients with Upper Normal Levels of Thyroid Stimulating Hormone?" HFSA-September 18-21, 2005, Boca Raton, Florida
84. Poster presentation-"Quality of Life in Patients Implanted with the HeartMate II Left Ventricular Assist Device for Severe Heart Failure" -HFSA, September 18-21, 2005, Boca Raton, Florida
85. Poster presentation- "A New Therapeutic Option for Women in Advanced Heart Failure: Results of the HeartMate II Continuous Flow Left Ventricular Assist Device Clinical Pilot Study"-HFSA, September 18-21, 2005, Boca Raton, Florida
86. Poster presentation- "Improved Outcomes with Chronic Inodilator Therapy in the Advanced Heart Failure Patients"-HFSA, September 10-13,2006, Seattle, Washington
87. Invited speaker - University of Texas Southwestern Medical Center Cardiology Grand Rounds: New Mechanical Support Strategies for Heart Failure - January 4, 2007, Dallas, Texas

MIMI VEGA 01575

*Reynolds M. Delgado III, MD, FACC*  
Page 25  
10/19/2009

88. Course Director and Moderator, Heart Failure Symposium Concepts in Contemporary Cardiovascular Medicine 2007. April 18, 2007. Houston, Texas.

89. Course Director and Moderator, Heart Failure Symposium Concepts in Contemporary Cardiovascular Medicine 2008. April 7-10, 2008. Houston, Texas

90. Reduction of Systemic Vascular Resistance Predicts a More Favorable Outcome in Patients with Severe Acute Decompensated Heart Failure: Insights from the MOMENTUM Trial" has been accepted for presentation at the 12th Annual Scientific meeting of the Heart Failure Society of America. September 21-24, 2008, Toronto, ON, Canada

91. Poster presentation – Weaning from Mechanical Cardiac Support in Patients with End Stage heart Failure Role of Dobutamine Stress Study. *21<sup>st</sup> Century Treatment of Heart Failure: Synchronizing Surgical and Medical Therapies for Better Outcomes*, October 16-18, 2008.

92. Course Director and Moderator, Heart Failure Symposium, Concepts in Contemporary Cardiovascular Medicine 2009, April 15-17, 2009, Houston, Texas.

93. Invited Speaker. Gordon Research Conference-Assisted Circulation 2009. September 9. Waterville Valley, New Hampshire.

MIMI VEGA 01576

Reynolds M. Delgado III, MD, FACC  
Page 26  
10/19/2009